

REMARKS

Claims 78, 98-115, and 119-123, are pending in the present application. Claims 1-77, 79-97, and 116-118, have been canceled without prejudice or disclaimer. Claims 119-123 have been newly added.

The specification has been amended at page 1, as requested by the Examiner to reflect the claim for priority under USC § 371. No new matter has been added.

Claim 78 has been amended, for the sole reason of advancing prosecution. Applicants, by canceling or amending claims, make no admission as to the validity of any rejection made by the Examiner against any of these claims. Applicants reserve the right to reassert any of the claims canceled herein in a continuing application.

Claim 78 has been amended as follows:

A method for changing the temperature of a biological matter sample from an initial temperature via an intermediate temperature to a final temperature, one of the initial and final temperatures being above the freezing point of said sample biological matter and the other being below the freezing point, comprising

providing said biological matter in the form of a sample whose the minimal dimension of the sample in each of two mutually perpendicular cross-sections exceeding exceeds 0.5 centimeters, and at least one of the cross-sections having an outer zone and an inner zone, the method comprising such that the temperature of the sample in the outer zone changes quicker than that in the inner zone, and

changing the temperature of said sample by the following steps:

- (i) changing the temperature of the sample by subjecting it to a temperature gradient from the initial temperature to the intermediate temperature until the temperature of the sample in at least one part of the outer zone equals the intermediate temperature whilst the temperature of the sample in the inner zone ~~or in another part of the outer zone~~, is different from said intermediate temperature;
- (ii) further changing the temperature of said sample by subjecting it to the intermediate temperature until the temperature of said sample in

at least one cross-section is uniform and equals the intermediate temperature; and
(iii) changing the temperature of said sample until the majority of said sample is at the final temperature.”

Claim 78 has been amended to recite one of its preamble features in the body of the claim, as well as to indicate that the temperature of the sample's outer zone changes quicker than that of the inner zone. Support for this feature appears in the present specification on page 7, lines 21-22 (PCT text), as well as throughout the specification and claims as originally filed. No new matter has been added.

Claims 119-123 have been newly added. Support for new claims 119-123 appears throughout the specification and claims as originally filed. Specifically, new claim 119 finds support at page 10, lines 25-27. Claim 120 corresponds to claims 78 and 101 rewritten in independent form; claim 121 corresponds to claims 78, 102, and 103 rewritten in independent form; claim 122 corresponds to claims 78, 101, and 105 rewritten in independent form; and claim 123 corresponds to claims 78 and 119 rewritten in independent form. No new matter has been added.

In view of the following, further and favorable consideration is respectfully requested.

I. At page 2 of the Official Action, The Examiner objects to the disclosure.

The Examiner asserts that the first paragraph of the specification should reflect the claim for priority under 35 USC § 371.

The specification has been amended at page 1, to reflect Applicants claim for

priority under 35 USC § 371. Accordingly, the Examiner is respectfully requested to withdraw this objection.

II. At page 2 of the Official Action, claims 78, and 98-115, have been rejected under 35 USC § 103 (a) as being unpatentable over US Patent No. 5,873,254.

The Examiner asserts that the '254 patent does not describe the size of the sample and that the generic description is not limited with regard to the size of the sample. The Examiner asserts that the exemplification of the size of the sample in the cited reference is "ABOUT 1 cm x 1 cm x 0.5 cm," and that the "use of the term "about" in the above exemplification "permits a variation of undefined range around this measurement at the very least to ABOUT 2mm, which is the size of the container." Lastly, the Examiner asserts that mere scaling up of a prior art process is not sufficient to patentably distinguish over prior art.

In view of the following, this rejection is respectfully traversed.

To establish a *prima facie* case of obviousness, the PTO must satisfy three requirements. First, as the U.S. Supreme Court very recently held in *KSR International Co. v. Teleflex Inc. et al.*, Slip Opinion No. 04-1350, 550 U. S. ____ (April 30, 2007), "a court must ask whether the improvement is more than the predictable use of prior art elements according to their established functions. ...it [may] be necessary for a court to look to interrelated teachings of multiple patents; the effects of demands known to the design community or present in the marketplace; and the background knowledge possessed by a person having ordinary skill in the art, all in order to determine whether there was an

apparent reason to combine the known elements in the fashion claimed by the patent at issue. ...it can be important to identify a reason that would have prompted a person of ordinary skill in the relevant field to combine the elements in the way the claimed new invention does... because inventions in most, if not all, instances rely upon building blocks long since uncovered, and claimed discoveries almost of necessity will be combinations of what, in some sense, is already known." (*KSR, supra*, slip opinion at 13-15.) Second, the proposed modification of the prior art must have had a reasonable expectation of success, determined from the vantage point of the skilled artisan at the time the invention was made. *Amgen Inc. v. Chugai Pharm. Co.*, 18 USPQ2d 1016, 1023 (Fed. Cir. 1991). Lastly, the prior art references must teach or suggest all the limitations of the claims. *In re Wilson*, 165 USPQ 494, 496 (C.C.P.A. 1970).

Claim 78 has been amended and claims 119-123 have been newly added as discussed above. Claims 98-115 and 119 are either directly or indirectly dependent on independent claim 78. Further, new claims 120-123 incorporate the subject matter of claim 78.

Claim 78, as amended, is directed to a method for changing the temperature of a biological matter, and the first step of the method comprises: "providing said biological matter in the form of a sample whose **minimal dimension in each of two mutually perpendicular cross-sections exceeding 0.5 centimeters.**"

The above definition of the sample is an important feature of the presently claimed method. A person of ordinary skill in the art to which the presently claimed subject matter

applies, in view of the above definition, would understand that the sample is large because it exceeds 0.5 cm in all possible directions. In view of such dimensions, the temperature of the sample in its outer zone in each of its cross-sections changes quicker than that in the inner zone, as indicated in claim 78.

Claim 78 further lists steps of changing the temperature of the sample between initial, intermediate and final temperatures, in such a manner as to compensate for the above-mentioned difference in the thermal behavior of the outer and inner zones of the sample.

Thus, claim 78 recites:

*"changing the temperature of the sample ... until the temperature of the sample **in at least one part of the outer zone** equals the intermediate temperature whilst the temperature of the sample **in the inner** zone is different from said intermediate temperature";*

*"further changing the temperature of said sample by subjecting it to the intermediate temperature **until the temperature of said sample in at least one cross-section is uniform** and equals said intermediate temperature"; and*

"changing the temperature of said sample until the majority of said sample is at the final temperature".

The method of claim 78 is a result of the inventors' realization of the fact that in complete contrast to small samples whose outer and inner zones change their temperatures simultaneously, the temperature of a large sample does not change uniformly. In a large sample, the rate of temperature change at the inner zone is limited by the rate of heat transfer through the outer zone of the sample.

To overcome this, the method according to claim 78 includes bringing the sample to

the intermediate temperature by first allowing at least a part of the outer zone of the sample to be brought to the intermediate temperature whilst the inner zone or another part of the outer zone has a temperature different from the intermediate temperature, and then ensuring uniformity by subjecting the sample to the intermediate temperature until the temperature in at least one cross-section, and preferably in all cross-sections perpendicular to the direction of movement of the sample, is uniform.

The '254 patent describes a method of changing the temperature of a biological matter. The '254 patent does not teach or suggest "providing said biological matter in the form of a sample whose **minimal dimension in each of two mutually perpendicular cross-sections exceeds 0.5 centimeters**". Consequently, in complete contrast to the method of claim 78, US '254 does not address the issue of the temperature of the sample in its outer zone in each of its cross-sections changing quicker than that in the inner zone.

Regarding the size of the sample, the Examiner points out that:

- (a) the cited reference lacks the stipulation of the size of the sample and the generic description of the invention is not limited with regard to size of the sample;
- (b) exemplification of the size of the sample in the cited reference is "ABOUT 1cm x 1cm x 0.5cm", and the "use of the term "about" in the above exemplification "permits a variation of undefined range around this measurement at the very least to ABOUT 2mm, which is the size of the container";
- (c) mere scaling up of prior art process is not sufficient to patentably distinguish over prior art.

Regarding the Examiner's assertion (a) above, it is irrelevant whether the generic description of the '254 patent is or is not limited to size of a sample. It is however important

that all of examples of the '254 patent as well as the Background (col. 2, lines 9-10) describe only to the use of "straws" which are "commercial cell packaging" (col. 2, lines 9-10), and it is indicated that these straws (straws 38) have rectangular cross-sections of about 1 cm wide and about 2 mm high.

Regarding the Examiner's assertion (b) above, contrary to the Examiner's assertion, the '254 patent does not recite "0.5cm." Rather, the '254 patent recites, in col. 6, lines 13-14, that the size of the sample is "*about 1cm x 1cm x 0.5mm*."

Applicants note that, with the sample in '254 having its smallest dimension about 0.5mm, it is clear that there is a drastic difference between the size of the '254 sample and the size of the present sample according to claim 78, since the minimal dimension of the present sample is at least 10 times greater than the minimal dimension of the sample described in the '254 patent. Such a large difference is clearly not encompassed by the "use of the term "about" in the exemplification cited by the Examiner even if, as suggested by the Examiner, the minimal dimension of 0.5mm of the sample in '254 is replaced by the straw's height of 2mm.

Regarding the Examiner's assertion (c) above, the method of claim 78 can by no means be considered as mere scaling up the process of '254. This is because '254 does not teach or suggest a sample having at least one cross-section in which the outer zone changes its temperature quicker than its inner zone, as presently claimed. On the contrary, with the small height of the sample of '254 as described above, the speed at which the outer and inner zones of the sample in any cross-section thereof change their temperature,

is essentially the same. It is therefore not suggested by '254 to *subject the sample of '254 to the intermediate temperature until the temperature of the sample in said cross-section is uniform and equals the intermediate temperature.*

Accordingly, it is submitted that nothing in the '254 patent renders the subject matter of claims 78, 98-115, and 119-123, obvious within the meaning of 35 USC § 103. Thus, the Examiner is respectfully requested to withdraw this rejection.

In addition, with regard to present claims 101, 103, 105 and 119-123, Applicants further submit that these claims are fully patentable over the '254 patent in view of the above remarks and because the '254 patent does not teach or suggest the following presently claimed features: subjecting the sample to the intermediate temperature in a region with this temperature, whose length along the direction of movement of the sample, is not less than the length of the sample in this direction, as defined in claim 101; or in a region with such conditions as to allow the sample, at each cross-section perpendicular to this direction, to reach the intermediate temperature by the time the sample moves out of said region, as defined in claim 119; or pausing the movement of the sample in step (i) as defined in claim 103, or step (ii) as defined in claim 105.

In view of the foregoing, it is submitted that nothing in '254 renders the presently claimed subject matter obvious within the meaning of 35 USC § 103. Accordingly, the Examiner is respectfully requested to withdraw this rejection.

CONCLUSION

Applicants assert that the claims are in condition for immediate allowance and early notice to that effect is earnestly solicited. Should the Examiner deem that any further action by Applicants' undersigned representative is desirable and/or necessary, the Examiner is invited to telephone the undersigned at the number set forth below.

In the event this paper is not timely filed, Applicants petition for an appropriate extension of time. Please charge any fee deficiency or credit any overpayment to Deposit Account No. 14-0112.

Respectfully submitted,

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